KCI

510 (k) Summary

K971548

I.	**Name of Device:**	**Ambulatory V.A.C**
II.	**Classification Name:**	Powered Suction Pump (per 21 CFR 878.4780)
III.	**Substantial Equivalence:**	V.A.C. Plus, 510(k) No. 945062

MAY 22 1997

IV. Device Description:

The Ambulatory V.A.C. is a portable suction device that can be powered by a separate battery pack or a low voltage power adapter. When activated, it applies continuous or intermittent negative pressure to a wound, promoting wound healing and drainage of fluids and/or infectious materials from the wound into a disposable collection canister.

The Ambulatory V.A.C. consists of a small housing that contains a vacuum pump and control system with a containment chamber for a disposable wound fluid collection canister, and sterile, single-use disposables. Accessories included in the Ambulatory V.A.C. system are separate battery packs, a battery charger, an optional modem and a carrying belt and pouch. The disposables consists of the wound fluid collection canister with an integral hydrophobic filter and an attached length of multi-lumen tubing, a wound dressing pad, and an overlying adhesive film that adheres to the skin surrounding the wound.

The Ambulatory V.A.C. pump housing comprises of a compact plastic molding that weighs approximately 500 grams and measures 15 cm x 11 cm x 6 cm. When in use, the pump can be placed inside the pouch and carried on the belt or, when the patient is stationary, the pump can be placed on a table or flat surface.

The pump is turned ON by applying power either by the battery pack or the low voltage adapter. An LCD and membrane keypad on the top of the unit becomes active when power is applied. Operating parameters are selected using the LCD and keypad. The LCD is also used during operation to display the current negative pressure being applied and any alarm condition messages.

The Ambulatory V.A.C. automatically stores the operating parameters from the previous therapy session. When the Ambulatory V.A.C. unit is initialized, the LCD displays the phrase "NEW PATIENT" at the top the display with "NO" and "YES" beneath it. "NO" is displayed over the left-arrow key and "YES" is displayed over the right-arrow key. Both arrow keys are located directly below the LCD. If the left-arrow key is pressed, for NO, the phrase "Will operate at previous settings" is displayed on the LCD. The operating parameters for the current therapy session remain as they were for the previous session. The THERAPY ON/OFF key, located to the left of the LCD, is then pressed to begin therapy.

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If the right-arrow key is pressed for YES, indicating a new patient, the phrase "USING DEFAULTS" is displayed on the LCD. The user must specify whether default or user-selected parameters are to be used for the current therapy session. To use default parameters and begin operation, the THERAPY ON/OFF key is pressed and the unit will operate at default settings of 125mmHg with continuous therapy. To specify new parameters, the SELECT OPTIONS key, located to the right of the LCD, is pressed. The LCD displays the words "VAC TARGET =" followed by a number representing the current vacuum pressure setting. Pressing the right-arrow key increases the current setting in 25mmHg increments, while pressing the left-arrow key decreases it in 25mmHg increments. When the desired vacuum pressure is displayed, the SELECT OPTIONS key is again pressed to save the setting.

The LCD next displays a choice of two operation modes: 1) continuous and 2) intermittent. The word "CONTIN." appears over the left-arrow key and the word "INTERMIT." appears over the right-arrow key. The currently selected mode flashes on and off. To select continuous mode (if it is not already the currently selected mode), the user presses the left-arrow key and then the THERAPY ON/OFF key, to begin operation. If the continuous mode is already selected, the user simply presses the THERAPY ON/OFF key. To select the intermittent mode (if it is not already the currently selected mode), the user presses the right-arrow key and then the THERAPY ON/OFF key to being operation of therapy ON for 5 minutes and OFF for 2 minutes. The Ambulatory V.A.C. runs continuously until the THERAPY ON/OFF key is again pressed.

The Ambulatory V.A.C. pump has the following Alarm functions:

- Canister Full
- Dressing Leak
- Battery Low

Each alarm condition is accompanied by an appropriate LCD message and an audible alarm that can be silenced by correcting the condition or pressing the therapy button.

SINGLE USE DISPOSABLES

- wound fluid collection canister (50 ml) with integral filter and attached multi-lumen tube (flexible medical tubing, meets USP Class VI criteria)
- polyurethane foam pad
- plastic adhesive overlay
- Flexible tube to dressing connector

The wound fluid collection canister is a disposable chamber made of translucent plastic used for receiving fluids emitted from a wound. The canister includes a plastic cap that firmly locates the canister inside the pump housing. The canister is also graduated to allow the user to easily view and measure the volume of wound fluids within the canister.

The collection canister has two parts which locate on spigots inside the pump housing. One spigot is used for applying a vacuum down the central bore of the multi-lumen tube. The other spigot locates in the second port which in turn is connected to the outer lumen of the tube and is used for sensing negative pressure at the wound site. A 0.2 micron hydrophobic membrane filter is mounted over the canister outlet. Fluid is drawn up through the central bore of the tube and into the canister. When the canister becomes full, the face of the filter is occluded and the negative pressure is reduced at the wound site which triggers the canister full alarm.

The disposable wound pad is fabricated from either polyurethane or PVA foam. In order for wound fluids to be communicated into the canister, the pad must be secured over the wound. This is accomplished by applying a plastic adhesive drape over the wound pad that gently adheres to the skin surrounding the wound. With the wound area sealed, vacuum pressure is transmitted to the wound when the suction pump is activated.

INDICATIONS FOR USE

The Ambulatory V.A.C. is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

CONTRAINDICATIONS

The Ambulatory V.A.C. suction device is contraindicated for the following types of wounds:

- Fistulas, excluding blind or incomplete fistulas,
- Presence of necrotic tissue (including bone osteomyelitis),
- Skin Cancer.

PRECAUTIONS

- Patients on anticoagulant, or difficult hemostatis

DIFFERENCES BETWEEN CURRENT AND PREDICATED DEVICE

	[redacted]	V.A.C. Plus
DESCRIPTION	Pump unit carried on belt with separate battery pack	Hand carry, portable pump unit
WEIGHT	1.1 pounds	10 pounds
POWER	Battery powered or low voltage adapter, 115V/60Hz	115V/60Hz
THERAPY SETTINGS	Range 0-125mmHg	Range 0-125mmHg
CONTINUOUS AND INTERMITTENT THERAPY SETTING	Custom settings range from 30 secs. to 10 min. for ON/OFF times	Custom settings range from 30 secs. to 10 min for ON/OFF times
EXHAUST FILTER	YES	YES
SETTINGS LOCKOUT	YES	YES
PUMP TYPE	Oil-less Diaphragm	Oil-less Diaphragm
CANISTER CAPACITY	50 ml	300 ml
MICROPROCESSOR CONTROL	YES	YES
NEGATIVE PRESSURE FEEDBACK	YES	YES

Ambulatory V.A.C.
SPECIFICATIONS COMPARISON CHART

	AmbuVAC	VACPLUS	CARE E-VAC
MANUFACTURER/ DISTRIBUTOR	Kinetic Concepts, Inc.	Kinetic Concepts, Inc.	Aeros Instruments
MAX. PRESSURE		380mm/15" Hg	550mm/22" Hg
INDICATOR	Gauge	Gauge	Gauge
WEIGHT	2 lbs	10 lbs	9.7 lbs
FREE AIR DISPLACEMENT	2 liters/min	9 liters/min	27 liters/min
CYCLE	Intermittent and Continuous Option	Intermittent and Continuous Option	Continous
VACUUM VARIABILITY	Yes, Manual	Yes, Manual	Yes, Manual
TIME METER	Yes	Yes	No
EXHAUST FILTER	Yes	Yes	Unavailable
PUMP TYPE	Oil-less Diaphragm	Oil-less Diaphragm	Oil-less Diaphragm
POWER	115V/60Hz	115V/60Hz	110V/60Hz
DIMENSIONS	6"Wx4.3"Hx3"D	11"Wx12"Hx7"D	19"Wx11.5"Hx16.5"D
IN-TAKE HOSE	0.25" ID	0.25" ID	Unavailable
ILLUMINATED POWER SWITCH	Yes	Yes	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Mr. William H. Quirk
Director of Regulatory Affairs
Kinetic Concepts, Inc.
3440 E. Houston Street
PO Box 659508
San Antonio, Texas 78265-9508

Re: K971548
Trade Name: AmbuVAC Device
Regulatory Class: II
Product Code: BTA
Dated: April 24, 1997
Received: April 28, 1997

Dear Mr. Quirk:

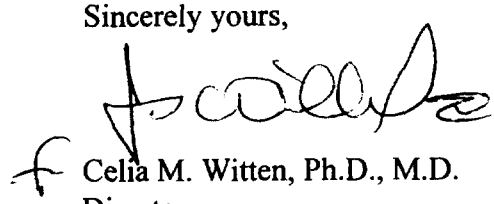
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971548

Device Name: Ambulatory V.A.C.

Indications For Use:

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NOTE: The Indications for Use of the Ambulatory V.A.C. are identical to the predicate device, VAC PLUS, 510(k)945062.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971548

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)